IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INSYS THERAPEUTICS, INC. and INSYS DEVELOPMENT COMPANY, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Insys Therapeutics, Inc. ("Insys Tx") and Insys Development Company, Inc. ("Insys Dev") (collectively, "Insys" or "Plaintiffs"), for their Complaint against Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd") (collectively, "Teva" or "Defendants"), hereby allege as follows:

The Parties

1. Insys Tx is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1333 South Spectrum Boulevard, Suite 100, Chandler, Arizona 85286.

2. Insys Dev is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1333 South Spectrum Boulevard, Suite 100, Chandler, Arizona 85286. Insys Dev is a wholly owned subsidiary of Insys Tx.

3. Upon information and belief, Teva USA is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1090 Horsham Road, North

Wales, Pennsylvania 19454. Upon information and belief, Teva USA is a wholly owned subsidiary of Teva Ltd.

4. Upon information and belief, Teva Ltd is a corporation organized and existing under the laws of Israel, having a principal place of business at 5 Basel Street, Petah Tikva, 49131, Israel.

Nature of the Action

5. This is a civil action for infringement of United States Patent No. 10,016,403 ("the '403 patent"). (Exhibit A.) This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq*.

Jurisdiction & Venue

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

8. Upon information and belief, Teva USA is a Delaware corporation and has a registered agent in the State of Delaware located at Corporate Creations Network Inc., 3411 Silverside Road, Tatnall Building Suite 104, Wilmington, Delaware 19810.

9. This Court has personal jurisdiction over Defendants, and venue is proper in this district, by virtue of the facts that, *inter alia*, Teva USA is a Delaware corporation and thus resides in Delaware, and Defendants have committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including in the State of Delaware. Defendants have indicated that they intend to engage in the commercial manufacture, use, or sale of a Fentanyl Sublingual Spray, 0.1 mg, 0.2 mg, 0.4 mg, 0.6 mg,

0.8 mg, 1.2 mg, 1.6 mg product ("the ANDA Product") under Abbreviated New Drug Application Nos. 210135 ("the '135 ANDA") and 211209 ("the '209 ANDA") (collectively, "the Teva ANDAs") before the expiration of the '403 patent, throughout the United States, including in the State of Delaware.

10. Upon information and belief, Teva Ltd is in the business of, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions, and through the actions of its agents and affiliates, including, at least, Teva USA.

11. Upon information and belief, Teva USA is in the business of, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions, and through the actions of its agents and affiliates.

12. Upon information and belief, Teva Ltd and/or Teva USA hold Pharmacy Wholesale Licenses from the State of Delaware, under License Nos. A4-0001447 and -0001468, and Distributor/Manufacturer Licenses for Controlled Substances from the State of Delaware, under License Nos. DM-0007115 and -0006546.

13. Upon information and belief, Teva Ltd and Teva USA have participated and collaborated in the preparation, filing, and seeking FDA approval of the Teva ANDAs for the ANDA Product; continue to participate and collaborate in seeking FDA approval of the Teva ANDAs; and intend to participate and collaborate in the commercial manufacture, marketing, offer for sale, and sale of the ANDA Product throughout the United States including the State of Delaware.

14. Defendants' infringing activities with respect to the filing of the Teva ANDAs and intent to commercialize the ANDA Product have led and/or will lead to foreseeable harm and injury to Plaintiffs.

15. This Court also has personal jurisdiction over Defendants, and venue is proper in this district, by virtue of the fact that, upon information and belief, *inter alia*, Defendants have availed themselves of the rights and benefits of Delaware law, and have engaged in systematic and continuous contacts with the State of Delaware.

16. This Court also has personal jurisdiction over Defendants, and venue is proper in this district, because they have previously submitted to the jurisdiction of this Court and have further previously availed themselves of this Court by initiating lawsuits, consenting to this Court's jurisdiction, and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Teva Pharms. USA, Inc. v. Mylan Pharms. Inc.*, C.A. No. 17-0249-GMS (D. Del.) (Teva USA and Teva Ltd filed complaint for patent infringement); *Teva Pharms. USA, Inc. v. Doctor Reddy's Labs., Ltd.*, C.A. No. 16-1267-GMS (D. Del.) (same); *Teva Pharms. USA, Inc. v. Biocon Ltd.*, C.A. No. 16-0278-GMS (D. Del.) (same); *Teva Pharms. USA, Inc. v. Dr. Reddy's Labs., Ltd.*, C.A. No. 15-0306-GMS (D. Del.) (same); *Teva Pharms. USA, Inc. v. Amneal Pharms. LLC.*, C.A. No. 15-0124-GMS (D. Del.) (same); *Teva Pharms. USA, Inc. v. Synthon Pharms., Inc.*, C.A. No. 14-1419-GMS (D. Del.) (same); *Insys Therapeutics, Inc. v. Teva Pharms. USA, Inc.*, C.A. No. 17-1303-GMS (D. Del.) (Teva USA and Teva Ltd did not contest jurisdiction, and Teva USA filed a counterclaim); *Orexo AB v. Actavis Elizabeth LLC*, C.A. No. 17-0758-GMS (D. Del.) (Teva USA and Teva Ltd did not contest jurisdiction); *Momenta Pharms., Inc. v. Teva Pharms. USA, Inc.*, C.A. No. 17-0109-GMS (D. Del.) (same); *Amneal Pharms. LLC v. Teva Pharms. USA, Inc.*, C.A. No. 17-0074-GMS (D. Del.) (same);

Onyx Therapeutics, Inc. v. Teva Pharms. USA, Inc., C.A. No. 17-0449-LPS (Teva USA filed counterclaims and did not contest jurisdiction); *Bayer HealthCare, LLC v. Teva Pharms. USA, Inc.*, C.A. No. 16-1220 (D. Del.) (same).

Insys's NDA and the '403 Patent

17. Insys holds New Drug Application ("NDA") No. 202788 on SUBSYS® (fentanyl sublingual spray), and is the exclusive distributor of SUBSYS® in the United States.

18. On July 10, 2018, the '403 patent, entitled "Sublingual Fentanyl Spray" was duly and legally issued to Insys Dev. A copy of the '403 patent is attached as Exhibit A.

19. Insys Dev owns the '403 patent.

20. The '403 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for SUBSYS®.

Teva's ANDAs and Paragraph IV Notifications

21. Upon information and belief, Teva USA, with the collaboration or assistance of Teva Ltd, submitted the Teva ANDAs to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), including certifications with respect to the '403 patent under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Product prior to the expiration of the '403 patent.

22. Plaintiffs received written notification of Teva's ANDAs and its accompanying § 505(j)(2)(A)(vii)(IV) certifications by letters ("Paragraph IV Notifications"), both dated September 25, 2018, and both sent via Federal Express.

23. This action is being commenced by Plaintiffs within 45 days of the date of their receipt of the Paragraph IV Notifications.

24. Teva previously filed the '135 ANDA, seeking approval of a Fentanyl Sublingual Spray, 0.4 mg product ("the '135 ANDA Product"). Plaintiffs alleged infringement against Teva in Civil Action No. 17-1303 for submission of the '135 ANDA to the FDA under 21 U.S.C. § 355(j). The complaint in Civil Action No. 17-1303 further alleges that the '135 ANDA seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the '135 ANDA Product prior to the expiration of United States Patent Nos. 8,486,972; 8,486,973; 8,835,459; 8,835,460; 9,241,935; 9,289,387; 9,642,797; and 9,642,844 (collectively, "previously asserted patents"), and that the '135 ANDA contained a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the previously asserted patents, are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the '135 ANDA product.

25. Teva previously filed the '209 ANDA, seeking approval of Fentanyl Sublingual Spray, 0.1 mg, 0.2 mg, 0.6 mg, 0.8 mg, 1.2 mg, 1.6 mg products. Plaintiffs alleged infringement against Teva in Civil Action Nos. 18-414 (regarding the 0.1 mg, 0.2 mg, 0.6 mg, 1.2 mg, 1.6 mg products) and 18-1308 (regarding the 0.8 mg product) for submission of the '209 ANDA to the FDA under 21 U.S.C. § 355(j). The complaints in Civil Action Nos. 18-414 and 18-1308 further allege that the '209 ANDA seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the Fentanyl Sublingual Spray, 0.1 mg, 0.2 mg, 0.6 mg, 0.8 mg, 1.2 mg, 1.6 mg products prior to the expiration of the previously asserted patents, and that the '209 ANDA contained certifications,

pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the previously asserted patents are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the Fentanyl Sublingual Spray, 0.1 mg, 0.2 mg, 0.6 mg, 0.8 mg, 1.2 mg, 1.6 mg products.

26. The three civil actions described above, Civil Action Nos. 17-1303, 18-414, and 18-1308, were consolidated into a single civil action on September 27, 2018, under the caption Civil Action No. 17-1303-CFC CONSOLIDATED.

27. The information relating to the ANDA Product that was provided in Teva's ANDAs demonstrates that the ANDA Product, which Teva is asking the FDA to approve for sale in the U.S., will fall within the scope of issued claims of the '403 patent.

Teva's Infringement of the '403 Patent

28. Plaintiffs re-allege paragraphs 1–27 as if fully set forth herein.

29. By seeking FDA approval of the Teva ANDAs to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Product prior to the expiration of the '403 patent, Defendants have infringed that patent under 35 U.S.C. § 271(e)(2)(A).

30. Upon information and belief, the Teva ANDAs contain certifications under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '403 patent are invalid. Teva notified Insys of those certifications and provided statements of the alleged bases for them. Those statements, however, do not allege noninfringement of any claim of the '403 patent, separate and apart from Teva's assertions that claims of that patent are invalid.

31. Defendants are jointly and severally liable for infringement of the '403 patent under 35 U.S.C. § 271(e)(2)(A). Upon information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of the Teva ANDAs seeking to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Product prior to the expiration of the '403 patent.

32. Moreover, if Defendants manufacture, use, offer for sale, or import into the United States any of the ANDA Product, or induce or contribute to any such conduct, prior to the expiration of the '403 patent, including any applicable exclusivities or extensions, they would infringe one or more claims of the '403 patent under 35 U.S.C. § 271(a), (b) and/or (c).

33. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective dates of the approval of the Teva ANDAs be dates that are not earlier than the expiration date of the '403 patent, or any later expiration of any patent term extension or exclusivity for the '403 patent to which Plaintiffs become entitled.

34. Plaintiffs will be irreparably harmed by Teva's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Prayer for Relief

Plaintiffs request that the Court grant the following relief:

A. An order that Defendants have infringed the '403 patent by submitting the Teva ANDAs to the FDA;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective dates of any FDA approval of the Teva ANDAs will not be earlier than the expiration date of the '403

patent, or any later expiration of any patent term extension or exclusivity for the ’403 patent to which Plaintiffs are or become entitled;

C. An order permanently enjoining Defendants, their directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from manufacturing, using, offering to sell, selling, marketing, distributing, or importing the ANDA Product identified in this Complaint, or any product that infringes the ’403 patent, prior to the expiration of the ’403 patent, including any extensions to which Plaintiffs are or become entitled;

D. That Plaintiffs be awarded monetary relief to the extent Defendants commercially manufacture, use, offer for sale, or sell within the United States, or import into the United States any product that infringes or induces or contributes to the infringement of the ’403 patent, within the United States prior to the expiration of the ’403 patent, including any later expiration of any patent term extension or exclusivity for the ’403 patent to which Plaintiffs are or will become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest; and

E. Such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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